

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

3 IN RE: VALSARTAN PRODUCTS
4 LIABILITY LITIGATION

CIVIL ACTION NUMBER:

19-md-02875

ORAL ARGUMENT

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
September 8, 2022
Commencing at 11:00 a.m.

B E F O R E:

THOMAS I. VANASKIE (RET.) SPECIAL MASTER

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23 Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

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Judicial Law Clerk to The Honorable Robert B. Kugler

1 (PROCEEDINGS held via remote Zoom videoconference
2 before The Honorable Thomas I. Vanaskie, Special Master, on
3 September 8, 2022, at 11:00 a.m.)

4 THE COURT: Good morning, everyone. We'll get
5 started with our arguments on the matters that are pending.
6 There are two matters. One is in the nature of tying up loose
7 ends that have been loose for a number of months now, and that
8 concerns the request to unseal certain documents. We heard
9 argument on this on January 18th of this year, and as a
10 Special Master I made a number of rulings during the course of
11 that conference. There were, according to my notes and my
12 review of that transcript, two documents that had not been
13 addressed, had not been decided, whether they should be sealed
14 or not. One is the final GMC inspection report, Exhibit CC.
15 And the other is Exhibit 20 to ECF document number 1250, email
16 exchanges with an Italian pharmaceutical company, Menarini.

17 The first question I have -- and I'll ask both sides
18 this question -- is there a need for the Special Master, for
19 me, to issue an order that memorializes the rulings that were
20 made on January 18th? I think there are 11 documents at
21 issue; definitive decisions were made as to nine documents,
22 whether they should be sealed or unsealed. Do we need an
23 order that identifies those nine documents?

24 Will you be addressing this, Mr. Slater, since you're
25 on my screen?

1 MR. SLATER: Hello, Judge. How are you? Mr. Geddis
2 is going to argue this issue for us.

3 THE COURT: Okay.

4 MR. SLATER: I'll defer to him on this. Just -- I
5 would think that if an order could be entered just to avoid
6 any confusion, it always helps.

7 THE COURT: Yes.

8 MR. SLATER: That might depend a little on what
9 happens today, but I'll let Mr. Geddis address it as well. I
10 would think the answer is yes.

11 THE COURT: Mr. Geddis.

12 MR. GEDDIS: Hi, Your Honor. I think what Adam said
13 is correct. I think it would be helpful for us, and then for,
14 you know, with the class cert discussion going on with all
15 those documents, I think that group of attorneys would
16 probably like a concise statement of why those documents are
17 or are not confidential.

18 THE COURT: I wasn't intending to issue any
19 explanation. I've already made a determination. The
20 transcript is available. I could issue an order that says,
21 such-and-such document will remain sealed and such-and-such
22 document will be unsealed. I take it you would like that?

23 MR. GEDDIS: I think that would be best. Thank you.

24 THE COURT: Who's addressing this issue on the
25 defense side?

1 MR. COX: Good morning, Your Honor. Christopher Cox.
2 I will be arguing for the ZHP defendants. What Mr. Geddis
3 outlined makes sense to us, if there's an order that
4 memorializes Your Honor's rulings.

5 THE COURT: All right. We will promptly, hopefully
6 today, issue that order.

7 So let's proceed. We're going to hear arguments then
8 on what I understand to be the two documents that a
9 determination has not yet been made as to whether they should
10 remain sealed or not. One is the final GMC inspection report,
11 and the other is a series of emails involving ZHP and the
12 Italian pharmaceutical company or representatives of the
13 Italian pharmaceutical company Menarini.

14 Going back, and I know it's a number of months now, I
15 asked for letter briefs on the question of whether the final
16 GMC inspection report would be akin to an FDA inspection
17 report that could be requested under the Freedom of
18 Information Act here in the United States, whether there was a
19 European counterpart to FOIA. You did submit letter briefs,
20 and I'd like to hear brief argument on this issue.

21 Mr. Geddis, I'll turn to you first.

22 MR. GEDDIS: Thank you, Your Honor.

23 So I think it's clear that there is an equivalent on
24 FOIA -- well, to these documents. ZHP admits as much in their
25 February 8th, 2022 article -- excuse me, letter. On page 9

1 going on to page 10, they say: Although the applicable
2 exceptions to public accessibility provide an avenue for
3 disclosure of documents by the EMA where, quote, there's an
4 overriding interest -- overriding public interest in
5 disclosure, end quote. They argued that we can't meet that
6 standard, but I think it's clear that given the severity of
7 this recall, the worldwide nature of the recall, the public
8 has an exceptional interest in understanding what the EMA had
9 to say about it and understanding the deficiencies that were
10 found in ZHP, what ZHP -- how they responded, and ultimately
11 whether or not EMA thought that those responses were adequate.
12 So I think that exception does apply, and that, therefore, the
13 EU report should be held not confidential.

14 THE COURT: Regardless of what European law might
15 provide, do I have the authority to, nonetheless, order that
16 it be unsealed? It hasn't been produced, obviously.

17 MR. GEDDIS: I mean, the answer is, obviously, yes.
18 We argued, as you know, about whether or not it was just in
19 general subject to public disclosure as a court record, with
20 the public's presumption of a right to access. I think the
21 same public interests that apply under the EMA are even
22 stronger under our own law. And you actually asked ZHP to
23 provide a proposed redacted version of the report, and their
24 redactions are extremely overbroad. If you look at the -- at
25 their proposed redactions, on the third page they redact the

1 name of Baohua Chen. They redact the name of Jun Du. They
2 redact the name of Min Li. They redact the name of six other
3 people who were deposed in this case. They redact the fact
4 that there were nine major and eight other deficiencies later
5 on in the report, which is something that's discussed in the
6 Fierce Pharma article that we linked to in our February 8th
7 brief. And then, more generally, we also attached the FDA's
8 2018 inspection report to our letter on February 8. And that
9 contains extensive discussion of the same issues that all led
10 to the contamination. And all that information is public
11 there.

12 So the fact that ZHP was offered an opportunity to
13 provide a redacted version of this report -- and they
14 essentially redacted the entire thing except for the first
15 couple pages -- I think they've had a number of bites at the
16 apple at this point, and the Court should just order that the
17 report is public.

18 THE COURT: Thank you, Mr. Geddis.

19 Mr. Cox.

20 MR. COX: Thank you, Your Honor. First, we have no
21 indication that the public has access to this GMP inspection
22 report. What we do have is very clear evidence of the agency,
23 the EMA's intent that documents like this remain nonpublic
24 and the principles that the EMA considered in forming that
25 intent. And the EMA's reasoning and the conclusion are laid

1 out in the two documents that were the first two exhibits to
2 ZHP's February 8th submission to Your Honor. There's the
3 policy that the plaintiffs also submitted, policy 0043, and
4 the output tables. And Mr. Geddis writes in the letter and
5 talked about today that in principle all EU government
6 documents are publicly accessible and the EMA has, you know, a
7 policy of openness. That's true, but he ignores the EMA has
8 already considered those principles, those general principles
9 and specific principles in reaching the opposite conclusion
10 than the one plaintiffs urge and determined that the GMP
11 inspection report -- and this one and others like it -- are
12 presumptively nonpublic and non-releasable. And we described
13 in our letter the tables that reflect EMA's application of
14 their very principles that Mr. Geddis was talking about that
15 resulted in this 58 page document that explains the EMA's
16 thought process in determining that it's presumptively
17 nonpublic and non-releasable. And EMA explains the reason for
18 that, which is that it would undermine the purpose of the
19 inspections, investigations, and audits. It further indicates
20 that redaction is not applicable with respect to this category
21 of documents.

22 When you look at the report, EMA's conclusion makes
23 sense. It necessarily deep dives into a site's processes, and
24 the EMA can only conduct effective inspections if the sites
25 open their doors, provide information, information that is

1 necessarily specific, technical, private, and often
2 proprietary. That links up to the idea that redaction isn't a
3 ready-fix here because of the pervasiveness of the nonpublic
4 information that lands in these types of reports. And the EMA
5 writes these reports all the time and understands what's going
6 to end up in these reports.

7 THE COURT: I've read the report, Mr. Cox, and I have
8 trouble understanding what information that would be in that
9 report that would require protection of a federal court
10 sealing order.

11 MR. COX: Your Honor, I would focus on the testing
12 methods and procedures the same way you focus on -- and
13 manufacturing and quality control procedures. And, look, Your
14 Honor, we took into account your May 2021 order in determining
15 our position with respect to this document, and in the last
16 document that you addressed in that order you focused on the
17 testing methods and procedures that that document contained
18 and distinguished it from a document that included only
19 testing results. And I would say that this report is replete
20 with discussion not only of testing methods and procedures but
21 of manufacturing and quality control procedures. I mean, this
22 is the company opening its doors to a public agency to
23 understand what happened at these manufacturing sites. As Mi
24 Zu declaration states, a disclosure of this nonpublic
25 information that plaintiffs have not shown that the public has

1 would cause harm if disclosed to the public, including ZHP's
2 competitors.

3 THE COURT: You've proposed redaction -- I'm going to
4 come back to this because I have the report in front of me
5 now. You've proposed redaction of the major deficiencies that
6 were found. Why should that be redacted? I'm looking right
7 now, so the record is somewhat clear, at ZHP 02324740. It's
8 the fourth page, I believe, of the report, fourth or fifth
9 page.

10 MR. COX: Right. You're referring to the summary
11 sections, Your Honor, at the beginning.

12 THE COURT: You proposed redacting that information.
13 Well, your predecessor counsel did.

14 MR. COX: Yes, Your Honor. And I think the
15 description and the level of detail, the generality here, I
16 would agree is different than the discussion later in the
17 document, which really gets into the details of the testing
18 procedures, the manufacturing processes. I understand Your
19 Honor's point with respect to this summary section on the
20 pages ending 7470 and the first half of 741.

21 THE COURT: What would be the rationale for redacting
22 the company's response to these various deficiency findings
23 that were made?

24 MR. COX: I think the rationale is some of these
25 responses include discussions of internal standard operating

1 procedures of the company, internal processes, methods of the
2 company that are not public. And, again, we submitted a
3 declaration. The company believes that disclosure of those
4 internal processes would harm ZHP if they were made public,
5 including to its competitors.

6 And, you know, I think Mr. Geddis addressed the public
7 interest in disclosure. The EMA has issued a press release
8 about this report. It has made statements about this report.
9 I think that underscores the distinction between what the EMA
10 considers generalized information that, you know, is
11 appropriate for public release and the detailed information
12 that's contained in inspection reports like this, which again
13 the EMA presumptively protects categorically in the output
14 charts.

15 In plaintiff's letter they talk about the public
16 interest in disclosure of the identification of nitrosamine as
17 an API. I mean, that is available through numerous other
18 sources, the EMA's own press releases, other media reports.
19 We heard about Fierce Pharma: the FDA inspection documents the
20 plaintiffs have obtained through FOIA that were attached to
21 their letter; ZHP's internal documents that don't contain any
22 confidentiality designation and are publicly available.

23 So I think the public interest in disclosure such as it
24 exists has been more than satisfied.

25 THE COURT: I'm looking now at ZHP 02324745. I'm

1 looking at paragraph B. The inspection team reviewed the
2 documentation for complaint CC18004 received on 22 May 2018
3 from customer Novartis, in parenthesis, unknown peak detected
4 on 16 batches of valsartan.

5 In paragraph ii, it says: After being asked why no
6 direct comparison of the unknown peaks observed by Novartis
7 and their own GC chromatograms had been made, the company
8 stated that they were not in possession of the customer's
9 method at the time of the complaint. However, after review of
10 GC audit trails, it became evident that the company had
11 already obtained the Novartis method in December 2017. From
12 further checks on the communications between the company and
13 Novartis, it became evident that Novartis had shared their GCF
14 ID method with Zhuhai already in July 2017 as a means of
15 supporting investigations on unknown peaks.

16 Why should that be redacted? Why should that be
17 withheld?

18 MR. COX: Your Honor, I mean --

19 THE COURT: There's nothing detailed there. It
20 doesn't appear to be any secret method or testing approach.

21 MR. COX: Your Honor, I would return to EMA's intent
22 here and I think the principle that Your Honor has
23 acknowledged that there is deference to the agency's
24 application of its own principles. I mean, at the beginning
25 of the document we talked about sections that I agree with

1 you, you know, are not detailed, but categorically EMA has
2 said to encourage its own processes and to support its own
3 mission of protecting public health, that these documents are
4 categorically non-releasable and nonpublic.

5 THE COURT: Categorically non-releasable and
6 nonpublic. It's clear that unless you are a national of one
7 of the European countries, you would not have standing to seek
8 disclosure. Do we know for a fact that it's categorically
9 unreleasable? We don't have any declaration of an expert.

10 MR. GEDDIS: Your Honor, can I address that briefly?

11 THE COURT: You'll have your chance.

12 MR. GEDDIS: That's fine.

13 THE COURT: If I'm misspeaking, you can correct me,
14 but go ahead.

15 I'll hear from Mr. Cox, and then we'll hear from you,
16 Mr. Geddis.

17 MR. COX: Your Honor, that's true that there isn't
18 any expert declaration before the Court, but I think the
19 output tables are very clear. I mean, there are definitions
20 that are provided with respect to what non-releasable and
21 nonpublic are. I mean, there is a process where someone
22 within the EU can make an application for access to materials,
23 but the EMA would have discretion to reject such an
24 application based on the very principles that it used to
25 determine these were categorically nonpublic, including the

1 protection of commercial information and the protection of its
2 own -- the integrity of its own investigations.

3 THE COURT: Mr. Geddis made reference to the fact
4 that there is a presumption of access to court records, to
5 documents that are filed in a court proceeding and this final
6 GMC inspection report is an exhibit filed in the court in this
7 action. Why isn't that a controlling presumption here? That
8 is, that there should be public access to a judicial record.

9 MR. COX: Well, I mean, I think that is a presumption
10 that Your Honor had laid out in his May 2021 order. But
11 that's a presumption that could be overcome, and we believe it
12 has been overcome by the provision of Me Zu's declaration
13 stating that this nonpublic information that is contained
14 within the report -- and there clearly is nonpublic
15 information in the report -- would cause harm to ZHP.

16 THE COURT: Thank you.

17 Mr. Geddis, I'll hear from you now.

18 MR. GEDDIS: Thank you, Your Honor.

19 So just starting out with this EMA issue, which I think
20 is a bit of a red herring, as you emphasized, but I just want
21 to make the record clear. The first page of this chart says
22 that the document is, quote, not legally binding. And then if
23 you look at the pages that they highlight in their letter
24 regarding these investigation reports, it says that the
25 authority for those -- for that information -- excuse me. Let

1 me get to it.

2 THE COURT: What document are you referring to now,
3 Mr. Geddis?

4 MR. GEDDIS: I'm on the -- in the February 8th, 2022,
5 letter.

6 THE COURT: Okay.

7 MR. GEDDIS: And their Exhibit B, the first page,
8 says that the chart is not legally binding.

9 THE COURT: Right.

10 MR. GEDDIS: And then it says that the authority for
11 the position that the report shouldn't be released is article
12 4.2, third indent.

13 If you go to page 58 of that chart, to note five, this
14 is a quote of that authority. However, the authority indent
15 is actually an incomplete quote because if you go to the
16 actual EMA article, it also says, quote, unless there is an
17 overriding public interest in disclosure. And that's why ZHP
18 concedes on page 9 and 10 that it is possible that there could
19 be an overriding public interest in disclosure and that the
20 EMA would, therefore, release it.

21 That's also stated in Exhibit A on page 9 where there's
22 a list of exceptions. And bullet 2 says -- has the full
23 language where it says, the EMA shall refuse access to a
24 document where it determines that disclosure would likely --
25 would be likely to undermine the protection of subsection C,

1 the purpose of inspections, investigations, and audits unless
2 there's an overriding public interest and disclosure.

3 And that's why this is essentially a red herring
4 because that public interest and public disclosure essentially
5 leads us right back to where you wanted us to be, which is the
6 Avandia standard that there is a presumption of public access.
7 I think in the past we focused on the Third Circuit decision,
8 but I think it's also helpful to look at what happened on
9 remand at the trial court.

10 THE COURT: Right.

11 MR. GEDDIS: The court unsealed all 55 documents,
12 including clinical studies, GSK submissions to the FDA,
13 internal GSK emails and letters, records of teleconferences
14 between GSK and the FDA, and Avandia presentations and plans.
15 This completely contradicts this idea that ZHP is advocating
16 that if it's not public already, it has to be maintained as
17 confidential in this court. That goes against the presumption
18 of the public's right to access and is not supported by the
19 law at all. And that's why they had to submit their
20 declaration. And in this case the declaration is completely
21 conclusory and doesn't explain how they could be harmed. And
22 I've already said they were given a chance to present
23 redactions and they're extremely overly broad, as you already
24 pointed out. And even during this oral argument, ZHP hasn't
25 been able to point to anything specifically that should be

1 redacted in any sort of limited way, and, therefore, I think
2 the whole report should be held not confidential.

3 THE COURT: You concede that any of the proposed
4 redactions are appropriate?

5 MR. GEDDIS: No. I agree with Your Honor that I
6 looked at the report, and I didn't see anything that had this
7 type of specificity that would give any of their competitors
8 an advantage, especially at this point.

9 THE COURT: I may have made that statement, but I'm
10 looking now at starting at -- do you have the report available
11 to you, Mr. Geddis?

12 MR. GEDDIS: Yes.

13 THE COURT: I'm looking at ZHP 0234779. It's at the
14 end, or near the end, and it's a list of API products at the
15 Zhejiang API site.

16 MR. GEDDIS: I'm looking at it, Your Honor. I don't
17 think the product codes, which are things that are put in the
18 batch records that are given to customers, is anything that
19 would give some other competitor an advantage. It's, I think,
20 to most people completely meaningless information. And given
21 the public's right to access, there's no reason to redact it
22 from the public record.

23 THE COURT: I'll go a few more pages in at ZHP
24 02324783. The API structure of various products.

25 MR. GEDDIS: The API is essentially the -- it's the

1 chemical structure of the product. These are all generic
2 drugs. The chemical structure is public knowledge, and so
3 there would be no reason to redact those either.

4 THE COURT: Mr. Cox, do you want to respond on the
5 questions I was just asking?

6 MR. COX: Yes. Thank you, Judge.

7 First, let me say, I think some of the points that Your
8 Honor was asking about, I mean, it may be meaningless to the
9 public, but the point is that it may not be meaningless, would
10 not be meaningless to ZHP's competitors, and that's what we
11 submitted the declaration on in support of. And there's a 60
12 page report. There's absolutely information in here that
13 regards internal processes of ZHP manufacturing, quality
14 control. I understand that Your Honor may disagree with the
15 breadth of the redactions. I would respectfully request --
16 the redactions were done, as Your Honor acknowledged, by
17 former counsel. If Your Honor's inclined to release any
18 portion of this report, we respectfully request the
19 opportunity to revisit the proposed redactions made by prior
20 counsel, keeping in mind the many points that Your Honor has
21 been making during this oral argument, to pare those back.
22 But I do believe that there is information here that's not
23 appropriately disclosed to the public and to ZHP's
24 competitors.

25 THE COURT: Well, I don't think it's any secret that

1 I believe the document, in large measure, should be publicly
2 available as a judicial record. I'll do it reluctantly, but
3 I'd give you the opportunity to submit proposed redactions
4 that would be more consistent with the discussion I had. I
5 think the redactions proposed by prior counsel are just
6 overbroad and seek to keep from the public information that
7 would in no way cause any harm to ZHP, but would be essential
8 for someone to understand the context of the document itself.

9 So I've indicated I am going to direct that this
10 document be unsealed. I'm not persuaded by the chart that
11 accompanies the amassed description of documents that are held
12 confidential. I am persuaded by the presumption of public
13 access to judicial records, but recognize that commercially
14 sensitive and valuable competitive information needs to be
15 protected. So I'll give you that opportunity to submit
16 proposed redactions to me within seven days. That will be it
17 then, too. There won't be another bite at the apple on this
18 one. I'll make a determination based upon my review.

19 As I said, I went through this. Really the only thing
20 I came up with was the information starting at ZHP 02324779
21 and going over to 4787. I thought everything else could be
22 produced. So I expect what I'll see from you is something
23 that is much more tailored to protecting sensitive information
24 and not this overly broad effort to keep important
25 information, on a matter of great public interest, secret.

1 MR. COX: It will be more tailored, Your Honor. One
2 thing I would point out, and actually Mr. Slater pointed this
3 out in his letter and he attached the FDA inspection -- or an
4 FDA inspection report to plaintiff's letter. There are
5 pinpoint redactions, but there are redactions at almost every
6 single page of that document. So we will absolutely keep in
7 mind Your Honor's guidance here today and appreciate the
8 opportunity to have another bite at the redactions. But
9 consistent with FDA's own redactions, I think there are
10 redactions that are appropriate in this inspection report.

11 THE COURT: I think there could be redactions that
12 are appropriate, but they, as you say, need to be pinpointed.
13 The fact that they might appear on each page, that doesn't
14 mean much to me. The question is, what's being redacted? An
15 entire page should not be redacted because one line has
16 sensitive information that should be redacted. All right?

17 MR. COX: I understand that point, Your Honor. Thank
18 you.

19 MR. GEDDIS: Your Honor, for the record, that exhibit
20 was produced under FOIA. It was not redacted under the
21 standard of Avandia for a court record. So I think that ZHP
22 should not be using that as the standard by which to redact
23 the document. And if they're going to do that, then
24 plaintiffs would like to have an opportunity to review those
25 redactions and to respond, because I don't think that that

1 would be correct.

2 THE COURT: You have the right to review and respond.
3 So we'll give you seven days after you receive the proposed
4 redactions to respond. I will also say that the redactions
5 made by the FDA are intended to protect commercially sensitive
6 information or proprietary information, and even under
7 *Avandia*, that kind of information can be protected. All
8 right? All right.

9 Let's talk then about the email exchange that's
10 reflected in Exhibit 20 to ECF document number 1250.

11 I'll go to Mr. Cox first. Why should this remain
12 sealed?

13 MR. COX: Thank you, Your Honor. I know you heard
14 argument on this in January, so I will be more than brief on
15 it. But this is an email chain, as you can see: A long email
16 chain between ZHP and LCM Trading, who is affiliated with
17 ZHP's customer Menarini, a company in Italy. There are -- we
18 talked about redaction. I mean, certainly there are portions
19 of this document that I would absolutely not defend as, you
20 know, needing to remain nonpublic. There's discussions about
21 travel and logistics like that. I mean, a good bit of the
22 document is around that. I'm not here to argue that.

23 But, I mean, there are many discussions about
24 substantive issues related to these meetings that are going to
25 occur. And there's also --

1 THE COURT: I'm sorry. I am interrupting you and I
2 shouldn't. I was going to ask if you could point to one
3 substantive discussion that warrants redaction.

4 MR. COX: Sure. There's discussions on the very
5 first page about financial issues, losses related to certain
6 products, you know, right at the bottom of the first page of
7 the document. Later in the document there are also
8 discussions around, you know, alleged damages, potential
9 resolutions of those damages. And, you know, I think one of
10 the points that Your Honor was going to consider further after
11 the argument last time was that these are made pursuant to
12 confidentiality agreements between ZHP and LCM, and that's
13 substantiated by Me Zu's January 17, 2022, declaration.

14 And, Your Honor, in his May 24th, 2021, order,
15 considered the document to raise the very same issue. The
16 very first document that you address in that order raises this
17 issue. In the ruling to grant the motion to seal with respect
18 to that document, you were persuaded, as I understand it, by
19 third party privacy interests. The same third party privacy
20 interests apply certainly to some of the communications.
21 Again, I'm not someone who is going to drive to Florence or
22 fly to Florence. I'm not here to say that needs to remain
23 nonpublic, but that could be addressed through redactions.

24 THE COURT: Do you want to submit to me a redacted
25 version of this information that you think should be redacted?

1 MR. COX: I could do that, Your Honor. I think we
2 would be left, though, with something that really is talking
3 about logistics and back and forth between the company in
4 which there really is no interest -- public interest in
5 disclosure. And the substantive communications around
6 valsartan, those are communications that these two companies
7 agreed should remain between the two companies. So, I mean,
8 well, I'll pause that.

9 THE COURT: Mr. Geddis?

10 MR. GEDDIS: Just preliminarily, I am concerned about
11 this back and forth about redactions because this was subject
12 to extensive meet and confer between myself and ZHP. They
13 were given the opportunity to present me with redactions.
14 They did, in fact, offer redactions for other documents that
15 we were kind of waiting for these to be resolved and then
16 would go on to those. And they did not present them in this
17 case or for the last document. And it's just completely
18 inefficient and also contrary to local Rule 5.3 where if
19 you're making a motion to seal, you need to prove that there's
20 no less restrictive means to protect the interest that you're
21 advocating. And if there are, your motion is denied.

22 But with that said, this is a routine business
23 communication and, you know, this sort of information that ZHP
24 is discussing, such as damages, are not -- don't warrant
25 sealing. That's just ZHP trying to cover up its wrongdoing

1 and the consequences of its wrongdoing in this case, and the
2 public has an extremely high interest in understanding that,
3 to the extent possible. Especially, you know, where Baohua
4 Chen on the -- what is it? The -- on ZHP 01224767, it's
5 expected that Baohua Chen, the CEO of ZHP, is going to express
6 his regret for what happened and the willingness to listen and
7 to make a step towards Menarini's claims for damage.

8 And then finally, with respect to the confidentiality
9 argument, as you noted, Your Honor, at the last oral argument
10 you were reserving argument on that issue because we had
11 briefed it extensively with respect to an earlier motion to
12 seal. And in your decision on that motion to seal, with
13 respect to that argument on pages 11 through 13, you rejected
14 the argument that a confidentiality agreement between two
15 private entities rendered a document confidential. And you
16 cited *In Re: Forest Research Institute* case, which is a Judge
17 Kugler case. That stood for the same proposition that that is
18 essentially irrelevant. What matters is the substantive
19 content of the document and is that worth sealing. In this
20 case it doesn't warrant sealing and so it should be ruled
21 nonconfidential.

22 THE COURT: What document are you referring to? My
23 ruling --

24 MR. GEDDIS: Your ruling is from February 10, 2022,
25 ECF 1911.

1 THE COURT: Okay. All right. I'm not going to
2 receive another round of proposed redactions with respect to
3 this document. I'll issue a ruling, but I believe this
4 document should not be sealed. I think Mr. Geddis is correct
5 to point to my February 10, 2022 decision in recognizing that
6 the confidentiality agreements between two parties don't trump
7 the presumption of access accorded to judicial records. So we
8 will issue a written decision on it, but I don't see any need
9 to seal this document. All right.

10 I think that covers then the question of sealing of
11 documents. Is there anything else on this issue?

12 MR. GEDDIS: Your Honor, I just note, I think there
13 were 14 documents subject to the first oral argument. Just to
14 -- I would point you to our letter from -- let me find it --
15 January 17th. I listed them all and numbered them 1 through
16 14.

17 THE COURT: Are there documents that we have not
18 addressed?

19 MR. GEDDIS: Everything was handled. I think the
20 only -- they gave you a proposed redaction to Exhibit 28, and
21 that was the only -- that was by email on February 8th.

22 THE COURT: Okay.

23 MR. GEDDIS: Proposed redactions for Exhibit CC.

24 THE COURT: That's the exhibit we talked about today.

25 MR. GEDDIS: There was a second one, Exhibit 28, but

1 those redactions were extremely limited.

2 THE COURT: I have to address that yet, you're
3 saying?

4 MR. GEDDIS: I don't know if we need to have oral
5 argument on it, but I just wanted to flag it as something --

6 THE COURT: It's a loose end.

7 MR. GEDDIS: Yes. There's a lot of different
8 documents at issue.

9 THE COURT: Sorry. Is there anything else other than
10 Exhibit 28?

11 MR. GEDDIS: No, Your Honor.

12 THE COURT: All right. Anything else on your end,
13 Mr. Cox?

14 MR. COX: We'll submit to the Court and to plaintiffs
15 next Thursday -- or by next Thursday the redacted version of
16 Exhibit CC, and I thank you for that opportunity.

17 THE COURT: Okay. And we'll issue an order
18 memorializing that so that you have until next Thursday.

19 And then, Mr. Geddis, you'll have until the following
20 Thursday to give your response to the proposed redactions.

21 All right? All right.

22 Let's move on then to the motion for sanctions at ECF
23 1838.

24 Will you be arguing this, Mr. Slater?

25 MR. SLATER: I will, Your Honor.

1 THE COURT: All right.

2 MR. SLATER: Your Honor, I'm going to try to be brief
3 in my opening comments and then respond as necessary, because
4 I think that our briefs are very detailed and I think they
5 make our arguments very clearly. I'll just highlight a couple
6 points that I think that are important to set the groundwork
7 for whatever argument occurs today and whatever decision Your
8 Honor's going to make.

9 I really think that one of the logical starting points
10 is to look at what's been happening in this litigation.

11 Plaintiffs have been having their cases attacked and dismissed
12 for now I guess a year or two regarding what we would consider
13 to be technical deficiencies in plaintiff fact sheets, and the
14 defense has had no problem trying to have those cases
15 dismissed based on those discovery issues.

16 Now we have ZHP where -- with the Chairman of the
17 entire company not appearing for a deposition that Your Honor
18 has court ordered and some other issues with some documents
19 that Your Honor felt were important enough that you compelled
20 production of those documents.

21 The company has continued to sell their products in the
22 U.S. They're off the import alert, and per the document we
23 just talked about, we know that when Baohua Chen wants to
24 travel for business purposes, after the recall that was
25 October 2019, he's able to do it. So we have all that as a

1 background, and then I think that the next place to go really
2 is Judge Kugler's decision on the Chinese state secret
3 documents where Your Honor was affirmed. Judge Kugler was
4 very, very clear in what he believed the law to be and
5 affirmed Your Honor in that decision. And I thought a few of
6 the lines that he -- a few of the things he said on page 18 of
7 his decision, which is at 2021 Westlaw 6010575, that's the
8 Westlaw cite to Judge Kugler's decision.

9 THE COURT: I have it on my screen.

10 MR. SLATER: Terrific. I think on page -- asterisk
11 18 is just, I think, very instructive. I'll let Your Honor
12 get to that, but that's the page I'm looking at.

13 THE COURT: I'm there.

14 MR. SLATER: Thank you. If you look in the
15 right-hand column where asterisk 18 is, if you go down a
16 paragraph or two, the judge does a very detailed -- gives a
17 very detailed treatment of what really what he calls I think a
18 Catch-22 at one point or a legal rock in a hard place that ZHP
19 has basically embedded itself into and said, please, take
20 mercy on us. This isn't us; it's the government. And Judge
21 Kugler was very clear in rejecting that entire argument. He
22 was very clear that -- I'm quoting from him now -- PRC
23 defendants cannot enter the U.S. market expecting a possible
24 shield from unfavorable discovery by PRC blocking statutes.
25 As one judge's decision has implied, if you don't like the

1 rules, then stop doing business in the United States.

2 And the judge then, in the next paragraph said, you
3 risk serious consequences if you fail to obey a U.S. court's
4 order to compel discovery, and then talked about the fact that
5 the sanctions under Rule 37 are clearly enumerated and
6 available.

7 And that really is the roadmap for this motion. I
8 can't imagine a more clear situation. And even with the
9 passage of time, there still has been nothing done. I think
10 that we may hear arguments about whether it was a prior law
11 firm, or whatever, or maybe there will be arguments about how
12 important really is Mr. Chen. And I just want to foreshadow,
13 Mr. Chen's importance to this case has already been ruled on
14 by this court. The Court's already found he's an important
15 witness, already found that he has relevance to the specific
16 issues. And that's already been found in orders and his
17 deposition was court ordered. So the idea that we are now
18 going to decide whether or not he's an important witness, or
19 had relevant knowledge, I think if ZHP intends to argue that,
20 that's really a train that's left the station a long time ago.

21 So looking at all of the factors here and looking at
22 the law -- and, again, I'll reserve my right to respond,
23 depending on what ZHP says, but there's no reasonable sanction
24 that's going to deal with in this conduct other than what
25 we've asked for, which is a complete striking of ZHP's

1 pleadings and the finding that the allegations against ZHP are
2 proven. They can't shield their chairman from a deposition
3 under these circumstances and get away with anything less.
4 And this is a company, Your Honor, that we did a little
5 research on last week. Their market capitalization as of
6 August 25th is 4.2 billion dollars. So you're going to hear
7 ZHP, I would assume, say, well, you know, if you really feel
8 like you need to do it, give us a little monetary sanction.
9 But what number are you going to have to come up with to
10 impact a company with a market capital of over 4 billion
11 dollars? I would say we didn't ask for, as our request,
12 monetary sanctions, but if Your Honor were to go that way, the
13 number would have to be very, very substantial and would have
14 to be ongoing and would have to really hurt ZHP in a financial
15 way. It couldn't be -- a number that would hurt those of us
16 who don't have 4 billion dollars of market cap would be
17 meaningless to this company. And that's why we think at this
18 point, in light of the passage of time, in light of the clear
19 orders, the clear findings by this court and by Judge Kugler
20 on the state secret motion, which really speaks to the issues
21 here very clearly, we ask Your Honor to enter the sanctions
22 that we've requested and --

23 THE COURT: I would think an adverse inference
24 sanction along these lines that I'm going to say now would not
25 be appropriate. The adverse inference would be that the jury

1 would be able to draw an inference that ZHP was aware of the
2 contamination of valsartan earlier than July of 2017.

3 MR. SLATER: I think that there were probably some --
4 will be some devil-in-the-details-type discussions on what
5 that would mean. Obviously the question would be whether ZHP
6 could try to refute the inference. I think it would be --
7 that would be positive. I think it would be substantive.
8 It's certainly not what we're asking for. We are asking,
9 obviously, to go much further and to end the discussion
10 altogether. So to the extent Your Honor fashions a sanction
11 along those lines, we would just ask to make sure that it's a
12 bulletproof sanction where we're not going to end up still
13 trying the issue, if it were to come to that. Obviously, this
14 is highly discretionary with Your Honor, and we recognize
15 that, and we understand you want to try to get to what's the
16 meat of this and what are we really trying to accomplish? And
17 your point is well taken: Is there a way to just get right to
18 it? I would just ask that if Your Honor goes in that
19 direction, that it's a sanction with teeth that can't be
20 pulled off the bone at trial and that we don't end up still
21 litigating this inference. And more important, I think if
22 Your Honor does go in that direction and does not award the
23 full scale of sanctions we've requested, I think that that
24 litigation sanction in terms of how we would proceed in
25 substantive proceedings, including trial, I think that it

1 would also be important to accompany that with a very
2 significant sanction of funding as well -- of funds as well
3 because I think that ZHP needs to feel this now and they need
4 to understand. We understand how serious the federal courts
5 are, but I think ZHP at this point needs to see something
6 happen where they say, okay, we can't just keep buying time
7 and we can't assume we're going to get away with this.
8 Literally, what Judge Kugler talked to in his decision, and I
9 think we're here. I think that's where we've reached this
10 point.

11 THE COURT: Where do things stand with respect to the
12 production of Maggie Kong's custodial file?

13 MR. SLATER: It's an interesting question. What the
14 custodial file is, it would depend on whose definition you
15 come up with. ZHP says they've produced it, and they produced
16 the privilege log, I believe, and they say, we're done. We
17 will not be placated because that production, as Your Honor
18 knows from our papers -- but I know there's a lot of papers --
19 there were four documents. This is the specific assistant and
20 right hand to Baohua Chen. She has four documents in her
21 entire custodial file prior to June 28th, 2018, and we all
22 know that June is when everything broke. The four documents
23 before June 28th are dated in January and February of 2018.
24 So we're being asked to believe that she didn't have one
25 relevant document between January and February 2018 and June

1 28. So while this was all happening, she had no documents. I
2 find that very, very difficult to believe. There's nothing we
3 can do at this point because no other documents have slipped
4 through yet for us to be able to say, here, we have the
5 smoking gun. But on its face, it's very hard to understand
6 why that would be. So that's the status of Maggie Kong's
7 documents, Your Honor.

8 THE COURT: Is there anything still outstanding with
9 respect to the SMO 54?

10 MR. SLATER: I'll go through -- there's really the
11 four categories of documents. You've hit the one. The second
12 one was ZHP 02710347 in native with the metadata intact and
13 all nonprivileged documents bearing TC-201729. I'm just
14 trying to get that in for the court reporter a little slowly.

15 THE COURT: I know she appreciates it.

16 MR. SLATER: That item, the last that we left it, I
17 believe that they went back and said they're going to resume
18 their search. They're going to try to find more documents,
19 and to our knowledge we have not gotten a response to whether
20 they did so. So I don't think that answer has been given.

21 The third category I can hit is all drafts of the
22 irbesartan investigation report, with all the metadata intact,
23 obviously. We only still have the one version that we had
24 from the beginning that they found. It's a PDF. It's not
25 Word. There's no other drafts and there's nothing else. So

1 we don't believe that that order has been met, and we have
2 legitimate concerns, I think, at this point that the person
3 who was instrumental on that report and process, Mr. Lin,
4 there was no litigation hold for his files. So that's
5 something that jumps up as part of potentially the explanation
6 for why we're not getting anything else. But we don't believe
7 that production has been compliant.

8 The last is the remaining nitrosamine testing results
9 Your Honor ordered to be produced per Princeton 0075797. ZHP
10 at various times said they were scanning and producing
11 results. It was a massive amount of results. If Your Honor
12 recalls, we had a meet and confer on this, and we've never,
13 ever received any confirmation that what we were given is
14 complete. And we -- so we can't say that that's complete
15 either and we have serious questions about whether it is. But
16 certainly we would need ZHP to confirm for sure that all of
17 those documents were produced before we could say they were
18 compliant on that.

19 Those are, I think, the four categories of documents,
20 Your Honor.

21 THE COURT: The last category you were talking about,
22 these were the documents that had to be physically scanned, or
23 I'm trying --

24 MR. SLATER: Exactly. Test results that had to be
25 physically scanned.

1 THE COURT: Okay. All right. Thanks.

2 Anything else?

3 MR. SLATER: Not at this time, Your Honor.

4 THE COURT: All right. Who's addressing this issue
5 for ZHP?

6 MR. BERNARDO: I am, Your Honor. Richard Bernardo,
7 who renamed his picture there incorrectly spelling his own
8 name.

9 THE COURT: Mr. Bernardo.

10 MR. BERNARDO: Apparently, I need new contact lenses.

11 Before I get to the core aspect of this motion, Your
12 Honor, which is Mr. Chen, I would like to just address the
13 document issues because it has been --

14 THE COURT: I don't think that's the only issue. The
15 document issue is one that troubles me very much.

16 MR. BERNARDO: Understood, Your Honor, but I want to
17 address that preliminarily, is my point. My understanding is
18 that each of those document issues has been addressed; that
19 the material that exists has been produced; that good faith
20 searches have been made. And I'm obviously relying on
21 predecessor counsel, but I'm happy to meet with Mr. Slater to
22 go through that -- and I'll just say prove that out --
23 separately to address issues. But I come here, Your Honor,
24 with the understanding that ZHP, despite its objection to some
25 of those categories, has, indeed, complied with those

1 requests. The fact that Mr. Slater has raised issues, for
2 example, with his disbelief in whether a certain number of
3 documents exist or don't exist, or whether there should be or
4 shouldn't be a native version of another document, or things
5 that we can address. But they certainly don't provide the
6 basis for this court addressing them from a sanction's
7 perspective. And, again, I would welcome the opportunity to
8 dig further into that and to meet with Mr. Slater. And if
9 there are outstanding issues, to own them and address them
10 with the Court. But it's my understanding coming to this --
11 and I recognize those are important issues to Your Honor --
12 that those have been addressed by ZHP. So --

13 THE COURT: I am troubled by the fact that Maggie
14 Kong's file would only have four documents from January of
15 2018 to June of 2018. That just doesn't make sense to me.

16 MR. BERNARDO: Your Honor, I'm happy to look into
17 that. I apologize for not being prepared to address that
18 particular point. I was unaware that that was a specific
19 complaint as we've transitioned, but it's something I can
20 certainly look into. But I do believe, from my understanding,
21 is that due diligence and appropriate efforts were made to
22 locate documents. And I suspect, like with many things,
23 including my understanding of the memo, there could be an
24 explanation. I would welcome the opportunity to provide that,
25 if that is an issue.

1 THE COURT: Mr. Slater, are you open to meeting with
2 Mr. Bernardo on that?

3 MR. SLATER: Well, I'm certainly open to whatever
4 Your Honor wants me to do. I can say that I'm concerned --
5 and I foreshadowed this in my argument -- that we're not
6 getting definitive statements. We're getting quote-unquote
7 understandings, references to predecessor counsel, this
8 question about whether this issue was raised. It was clearly
9 in the papers. We've laid this issue out. There's no
10 surprise that we've been concerned about this -- about this
11 suspicious lack of documents.

12 Certainly, if they want to explain, they can try to
13 explain, but here we are at the argument date. This motion
14 and these issues have been pending now for a really long time,
15 and I'm concerned about ZHP just saying, well, let us keep
16 just trying to explain this. If they can't come in right now
17 and say, we definitively have confirmed that all of these
18 documents that were court ordered to be produced, including
19 the irbesartan draft report where we can't get anything with
20 actual metadata on it, an actual Word document, which harkens
21 back to the July 27th email. It just happened to be a PDF
22 without the metadata, and it just happened to be in one
23 person's file. The fact that these are patterns that have
24 repeated, I think that that should inform the Court's
25 consideration as well.

1 So I guess the short answer after the long answer is I
2 would prefer not to be in a situation where we have to now go
3 through ZHP, figuring out what they did or didn't do, when
4 they have never confirmed to the Court that they have complied
5 with that order. I think that the determination should be
6 they haven't complied. I think that -- because that's the
7 facts on the ground right now and that's all that's being
8 confirmed.

9 THE COURT: Mr. Bernardo.

10 MR. BERNARDO: Your Honor, I would disagree with
11 that, and I would say that the responding papers to this
12 motion did confirm, in fact, that the document issues were
13 being addressed and have been addressed. I -- again, I
14 apologize if it's perceived that I'm not prepared to address
15 them, but my preparation to address them was to investigate
16 whether or not all of those had been dealt with. And I take
17 Mr. Slater's point that I did preface my statement with "I
18 understand that," but, of course, that's really all I can do,
19 Your Honor, is to consult with prior counsel and to make a
20 confirmation. I can now do more, now that Mr. Slater has
21 raised that, and get a more definitive confirmation for the
22 Court, but I would appreciate the opportunity and fairness to
23 address that because I don't want to represent things on the
24 record. But I will say that I do have some understanding of
25 some of the issues, and I do believe that there are some

1 explanations for those just because I do understand that
2 they've been looked into. I was under the impression that
3 when the productions were made it was communicated that these
4 had completed the efforts, and I will check into that as well.

5 But, again, my point, Your Honor, is it's my
6 understanding that the document issues have been addressed
7 reasonably and appropriately, some over ZHP's objections, some
8 being made at risk of failure to comply with Chinese law in a
9 good faith effort. Some even made, Your Honor, when Your
10 Honor gave ZHP a chance to object to burden and substantiate
11 that objection. In good faith, ZHP, under the circumstances,
12 said, no, we're not going to come back and revisit that.
13 We'll absorb the burden and we'll produce these. And what I'm
14 referring to specifically are what you're describing as those
15 manually created nitrosamine testing documents. So I don't
16 think it is fair or appropriate to use those as a basis of
17 sanctions here when, in fact, it's my understanding coming to
18 this Court that they have been addressed.

19 Again, I would be happy to meet with Mr. Slater and
20 provide him with whatever he needs to certify or demonstrate
21 that. I acknowledge, Your Honor, that doesn't necessarily
22 mean that's the end of the scenario. In other words, once we
23 confirm that something certainly exists, there's a completely
24 separate and different issue that plaintiffs may raise with
25 the Court as to why certain things don't exist. But that's

1 different from not complying with a court order, Your Honor, I
2 would submit.

3 THE COURT: I think, Mr. Bernardo, it would be
4 appropriate to ask that your counsel for ZHP certify that they
5 have complied with Special Master Order 54, SMO 54. I think
6 the record should reflect that there's this certification that
7 conducted a diligence search and produced everything that you
8 ordered to be produced that we could find.

9 MR. BERNARDO: I think that's fair and appropriate,
10 Your Honor. I will embark to provide that.

11 THE COURT: All right. Thanks.

12 Let's talk about sanctions based upon the inability to
13 depose Mr. Chen.

14 MR. BERNARDO: Yes. Your Honor, I want to set the
15 table a little bit and focus on one particular word that Mr.
16 Slater used in his argument, which is the word "they." I
17 think he said, "they cannot shield a Chairman." I agree with
18 they cannot; ZHP cannot. But this is not a circumstance like
19 the risk that they would be at for failure to comply with a
20 state secret law where they could be fined or punished. This
21 is a circumstance where the Chinese government, not "they,"
22 not ZHP, prohibited Mr. Chen's travel, number one. Number
23 two, it would almost be like Your Honor going to the airport
24 without a passport, without a driver's license, or any form of
25 identification. There literally would be no way for him to

1 travel out of the country without being provided by the
2 Taizhou Exit-Entry Organization the appropriate documentation,
3 which they didn't provide. And I'll address all of that, but
4 I just want to start by making it clear that this is not
5 something where ZHP said, nope, we're not going to do it
6 because Chinese law tells us this. This is something where
7 Mr. Chen literally was without ability to travel out of the
8 country.

9 Your Honor, because of those circumstances, plaintiffs
10 are essentially asking this Court to give them a directed
11 verdict against ZHP in the entire valsartan litigation, and we
12 would say that that request is beyond the pale for several
13 reasons. First, throughout this, ZHP has acted in good faith,
14 particularly with respect to depositions in general, and Mr.
15 Chen's deposition in particular. Second, there is no
16 prejudice here sufficient to justify the severe sanctions that
17 plaintiffs are requesting. And, finally, any type of relief,
18 including with all respect, Your Honor, the type of adverse
19 inference that you were describing, I would argue would be
20 directly disproportionate to the circumstances here.

21 I don't think it's appropriate somehow. First, it's
22 not a tit-for-tat. But, second, to compare a plaintiff's
23 willful failure to abide by the most basic piece of discovery
24 that they have to abide by, to do it PFS, which I'm sure in
25 advance of not doing that they understood the consequences.

1 So I don't think that's quite the background or context in
2 which to evaluate this.

3 But I wanted to talk about -- because it's very
4 important -- that ZHP here, Your Honor, has at all times acted
5 in good faith to facilitate Mr. Chen's appearance at a
6 deposition. Plaintiffs suggest in their papers, with zero
7 evidence, that Mr. Chen somehow could have used his position
8 as Chairman of the Taizhou Federation to obtain permission to
9 leave the country. That's, first and foremost, completely
10 speculative and, equally important, absolutely wrong. And it
11 fails to take into account significant differences between the
12 structure and operation of the Chinese government and the
13 structure and operation of the U.S. government with which we
14 are all familiar. While Mr. Chen is the Chairman of that
15 federation, that is an honorary title that doesn't give him
16 power to make unilateral decisions. Just looking at the
17 various websites that are relevant to these organizations, you
18 see that that organization is led by the communist party of
19 China and there's a representative of the communist party of
20 China in that organization. And that organization, not Mr.
21 Chen as some honorary chair of that layer of the government,
22 has the authority to decide -- I'm sorry -- to permit or not
23 permit.

24 THE COURT: You've given me a lot of information
25 here.

1 MR. BERNARDO: Fair enough.

2 THE COURT: Is it appropriate that you're saying
3 this? Should there be a declaration of a witness, or
4 something that is evidentiary in nature? Go to websites to
5 look at information? That's something you get judicial notice
6 of or --

7 MR. BERNARDO: Your Honor, first, if that's a
8 deciding factor, we'd be happy to provide that, but I was
9 merely providing it to state what I think is obvious and to
10 refute what really is just rank speculation that plaintiffs'
11 counsel made in their papers in reply to ours.

12 I think, Your Honor, you need not look farther than the
13 fact that the organization that you would expect Mr. Chen to
14 have some influence over, which is the -- I'll call it the
15 lower level communist party committee within ZHP. In that
16 instance, they did, in fact, grant Mr. Chen's request. So if
17 you're going to look at the ability to influence, you have to
18 look at where that ability logically could stand.

19 But to your point, Your Honor, I would be happy to
20 submit some declaration to support that, because we are
21 talking about some very serious sanctions. We're talking
22 about basically ending the litigation against ZHP because
23 plaintiffs are speculating that given his numerous roles in
24 the Chinese government, he should have been able to influence
25 this decision. I simply am pointing out as a matter of common

1 sense and understanding and respect to the differences in the
2 way we understand government to operate in the United States.
3 And the way we all know the government operates in other
4 countries, including China, which is vastly different. We see
5 evidence of that on the news every day.

6 Your Honor, even while ZHP's motion was pending, the
7 apex motion, ZHP acted in good faith and started the process
8 of obtaining the government's permission. The communist party
9 that I spoke about initially granted the request in June, and
10 right after that ZHP, as it was required to do, went to the
11 next layer it was required to. And ZHP promptly notified the
12 court October 26th of the development that that organization,
13 the Taizhou Federation, denied the request.

14 But even more, Your Honor, after that -- and that's in
15 Ms. Lu's declaration -- ZHP continued to try and work with the
16 Chinese government to obtain authority, to see if they could
17 make an exception. And that's an evidence not of trying to
18 prevent this, but that's an evidence of trying to work with
19 the government.

20 Now, from the very beginning, plaintiffs have known
21 there's a risk of this happening and chose not to avail
22 themselves of the Hague Convention. I'm sure what we're going
23 to hear -- which is in their papers -- is, you know, that's
24 like playing the lottery. I mean, one in, you know, 30 years
25 has been granted. But that's not the point. The point was

1 there was no effort even made. It was determined that I don't
2 want to deal with that, or I don't like the restriction that
3 imposes. But if you're evaluating sanctions, Your Honor,
4 litigation-ending sanctions, you have to consider the fact
5 that there was an alternative path. Even the Court in its
6 December 21st hearing raised this other matter of the Hague
7 Convention, and Judge Kugler acknowledged that the root under
8 the Hague Convention might preclude -- quote, "might preclude
9 the imposition of sanctions."

10 Now, plaintiffs appear to suggest that he previously
11 found somehow that the Hague Convention is irrelevant to all
12 discovery disputes in the litigation. They cite to the
13 lengthy December 20th -- 21st decision In re: Valsartan.
14 But, Your Honor, they're misreading or misstating that Court's
15 decision. Judge Kugler only found that the Hague Convention
16 rules are not the, quote, "exclusive consideration" in a
17 court's decision to compel discovery, to order it, to produce
18 discovery, which is what that case was all about. That case
19 was all about producing documents and whether or not the Court
20 could order their production. That's a fundamentally
21 different question, Your Honor, from whether the parties'
22 failure to use the procedures prescribed by the Hague
23 Convention are a relevant factor for Your Honor to consider in
24 a determination of whether it's going to punish ZHP. In fact,
25 this distinction that I'm making is not made up. It's well

1 born in the case law. We cite to the Tenth Circuit case in
2 *Westinghouse* distinguishing between the power of court to
3 order discovery and the factors relevant there, and the
4 imposition of sanctions for failure to comply.

5 So, again, Your Honor, no bad faith. We have good
6 faith. And even after the PRC agencies denied Mr. Chen's
7 permission to travel, as I said, they continued to work with
8 him. And as further evidence of good faith, in demonstration
9 that they were trying to provide information, you'll note that
10 in their papers ZHP offered the possibility of providing a
11 written declaration setting forth responses to questions.

12 I say all that, Your Honor, because what we're really
13 talking about here is did ZHP do something wrong, or were they
14 basically the victim of -- poor word -- but were they
15 basically subject to a government that denied a request to be
16 deposed? As Your Honor knows, these deposition efforts were
17 quite difficult, and ZHP, as further demonstration of the good
18 faith it's acted in during this litigation, sought permission
19 and obtained permission from 12 other witnesses to travel from
20 China to outside the country at ZHP's expense.

21 THE COURT: I'm aware of that.

22 MR. BERNARDO: Your Honor, I will tell you,
23 obviously, I didn't represent ZHP at that time, but since I've
24 represented ZHP I've had to work to obtain clearance for
25 another witness to be able to testify. And I can personally

1 attest to the challenges presented there and the great efforts
2 ZHP made to facilitate that process. In fact, Your Honor may
3 recall, the company was concerned that notwithstanding their
4 clearance that they obtained because of the pandemic
5 restrictions at the time, they were concerned that Ms. Guo
6 could end up at the airport wouldn't let her go. So we sought
7 from Your Honor an order so she could have that in her purse
8 just in case -- notwithstanding the permission she was
9 granted -- there was a problem. And, of course, there wasn't
10 and she was deposed.

11 I say all that, Your Honor, because I think Mr. Slater
12 talks about context, but I want to talk about the context here
13 with respect to ZHP because what we're talking about is
14 punishing ZHP. As Mr. Slater said, give them a sanction so
15 they can understand the seriousness of this. But no sanction
16 is going to change a decision of the Chinese government to
17 permit or prohibit a deposition to occur.

18 Foreign law, as I said, not ZHP's conduct, is really
19 what has resulted in this outcome. And we cited to -- which
20 is an important case -- the *Rogers* case, the United States
21 Supreme Court case, because that shows that the United States
22 Supreme Court concluded it's inappropriate to sanction a
23 company by dismissing its lawsuit because a blocking statute
24 prohibits its compliance with the discovery order. It's the
25 exact same situation we had here. And the Court made it clear

1 that, quote, the inability to comply with foreign law is a
2 weedy reason for non-production of discovery materials. And
3 that was documents, not even compelling the witness. And the
4 notion that courts in the U.S. have discretion to exercise --
5 to excuse violations is also set out in the restatement which
6 we cite to.

7 The only case that plaintiffs cite to, Your Honor, we
8 would suggest and we pointed out, is this *Abiola* case, which
9 is really inapposite. This was a case where the single
10 individual who was accused of all -- directing all of these
11 atrocities on Nigerian citizens basically told them that he
12 would agree to be deposed. Never mentioned any issues with
13 respect to the possibility of the government prohibiting him,
14 and then all of a sudden reneged on that and used the
15 government as an excuse. That is not what is going on here.
16 That is bad faith. This is not bad faith.

17 Your Honor, even if somehow you're inclined to think
18 that the bad faith -- I'm sorry -- that the government's
19 decision could somehow be construed as bad faith on ZHP,
20 plaintiffs can't demonstrate prejudice here, which is another
21 requisite element to the type of sanctions that they're
22 seeking. To Mr. Slater's point, I'm not here to re-litigate
23 the apex motion. We understand the Court's decision.
24 However, that decision to order his deposition doesn't mean
25 that the absence of it necessarily prejudices plaintiff to the

1 point of basically a directed verdict against ZHP.

2 As the Third Circuit has explained in the *Spirit* case
3 we cite, the thrust of Supreme Court jurisprudence is that
4 sanctions that affect the outcome of a trial should only be
5 imposed in order to compensate for violations that may
6 plausibly be thought to likely affect the outcome of the
7 trial. And here, with the number of depositions that have
8 been taken in this case, including a deposition that lasted
9 over two days to address other issues that were raised, it
10 can't plausibly be stated that the absence of the deposition
11 of Mr. Chen will affect the outcome of this trial.

12 Particularly, Your Honor, when you look at the expert reports,
13 none of which, you know, were hampered in any way by the
14 absence of this testimony so there's no prejudice. The 17 ZHP
15 witnesses have been deposed on a multitude of topics.

16 And, again, I want to go to the prejudice and to the
17 point that I raised earlier. Your Honor has to consider the
18 fact that not even trying to get information from Mr. Chen
19 through another means that ZHP offered. That is, trying to
20 work together to come up with a declaration, as we did with
21 Ms. Guo's deposition, to negotiate stipulations, or something,
22 evidences the fact that they really don't need this because if
23 they really did and really believed this was outcome
24 determinative, they at least would have explored that
25 opportunity. Instead, they basically want a windfall.

1 Finally, Your Honor, the most important thing is
2 there's absolutely no relationship, no proportionality between
3 what resulted -- in other words, the Chinese government's
4 prohibition on his testimony -- and the requested sanction,
5 which is striking defenses. ZHP, as I pointed out, has gone
6 through great lengths, and imposing these sanctions would --
7 or any kind of sanctions effectively result in a windfall.

8 Your Honor, while we strongly disagree that any
9 sanctions are warranted, at best, monetary sanctions, and
10 certainly not of the type that Mr. Slater is requesting that
11 appears to be some portion of their net worth. Maybe it's the
12 cost of bringing this motion. But, Your Honor, again, I want
13 to go back to the first point I started with in conclusion,
14 which is you need to look at this in terms of what is really
15 going on, which is, you know, another government is making a
16 decision to withhold documentation for someone to travel.
17 That is not something that ZHP has control of. They made
18 efforts to try and get the government to change its mind and
19 failed, and it's totally inappropriate to punish ZHP through
20 striking its defenses, or even worse, through an adverse
21 inference that discusses a particular document or a particular
22 piece of evidence for which there's absolutely no evidence
23 that Mr. Chen could contribute additional information.

24 So in conclusion, Your Honor --

25 THE COURT: Let me see if I can phrase this

1 correctly. They look to the fact that ZHP has elected to do
2 business in the United States. United States has opened
3 discovery laws. It's been suggested by some that discovery in
4 civil litigation in the United States may have risen to the
5 stature of a right protected by the due process clause and ZHP
6 has chosen to do business here, that it has assumed the risk
7 that its government would preclude it from presenting or
8 making available a witness, or witnesses, the consequence of
9 which would be sanctions that cause it to lose the case.
10 Isn't that a risk that ZHP assumed by deciding to do business
11 in the United States?

12 MR. BERNARDO: No, Your Honor. I disagree with that.
13 I think it's a risk that they would assume if they would
14 actively choose to take a position. If they would actively
15 not provide something. But it should not be a consequence to
16 ZHP if the Chinese government does something because that's so
17 purely speculative as to whether that could occur. That
18 essentially would be telling any foreign corporation you
19 should not do business in the United States, which cannot
20 possibly be the public policy or outcome that would be
21 appropriate.

22 Again, while that's not the circumstance here, Your
23 Honor, I could see that argument being made -- and, in fact, I
24 believe it was made by plaintiffs -- if ZHP was choosing not
25 to do something. Because then you could weigh their two

1 choices. You chose to do business here, but now you're
2 choosing not to play by the rules. But that's not at all what
3 we're talking about. We're talking about them being precluded
4 from doing something.

5 So in conclusion, Your Honor, again, I think plaintiffs
6 have to show bad faith here for this type of sanction and for
7 any of the type that we're talking about. And they cannot
8 show it. They can speculate, but they cannot show it.

9 Plaintiffs cannot legitimately argue that they're prejudiced,
10 because if they were, then they would have done whatever they
11 could possibly do to secure his presence, or at the very
12 least, say, let's see what we could do about doing written
13 questions. That would be a plaintiff who felt as if they were
14 prejudiced. And then, of course, Your Honor, under these
15 circumstances, the types of sanctions being sought here are
16 just wildly disproportionate to the circumstance.

17 Thank you, Your Honor.

18 THE COURT: Thank you, Mr. Bernardo.

19 Mr. Slater.

20 MR. SLATER: Thank you, Judge.

21 I'll try to take in buckets a little bit of what Mr.
22 Bernardo talked about. The entire discussion about whether or
23 not ZHP acted in good faith or bad faith actually isn't even a
24 factor. I'm looking at Judge Kugler's decision where he cited
25 to the Activision case that said even if the party has made a

1 good faith effort to secure permission from the foreign
2 authorities to make -- the information available in that
3 effort has been unsuccessful, that the significant sanctions
4 are appropriate. So all these discussions -- all those
5 arguments really are red herrings. And we also know that
6 we've seen the form that was submitted. And I took a lot of
7 note when Mr. Bernardo talked about the fact that, well, with
8 this other deposition we got an order from you, Judge, and we
9 got that to make sure she can get out of the country. Well,
10 Judge, they got an order from you, too, about Baohua Chen.
11 You ordered him to be deposed and to appear for his
12 deposition. And their disclosure to the Chinese government,
13 to the organization or the committee or whatever it is that
14 Mr. Chen is, I think, the Chairman of, the part of the
15 government that refused to let him leave the country, doesn't
16 mention the order. Doesn't attach the order. Doesn't submit
17 it. It just says he has litigation issues he needs to address
18 as opposed to a federal court has ordered me to be deposed by
19 court order and this could end up in very significant
20 sanctions for my company. Please let me do this. There's
21 nothing like that. And they left the section for his
22 quote-unquote opinion as to why this was important blank. So
23 even if we did go to the good faith/bad faith, there are
24 things that on their face show a lack of good faith and a lack
25 of openness to try to get him to be deposed. Judge, we know

1 that ZHP doesn't want him deposed. I mean, the idea that
2 they're doing everything they can -- were they doing
3 everything they could when they blocked -- when they tried to
4 block the custodial file from being produced and objected to
5 his deposition to the point where they took these issues up to
6 Judge Kugler? I mean, so they've never wanted him to be
7 deposed. And I think that where we really come down to is --
8 before I get to the final upshot I want to say one other
9 thing. Counsel mentioned that there's no important evidence
10 that's going to come from Mr. Chen. There's no expert reports
11 that would say his evidence matters. Mr. Bernardo should read
12 the deposition testimony of David Chesney, ZHP's good
13 manufacturing practices expert who I deposed, who wrote an
14 article about the fact that the top executive in the
15 company -- in this case Baohua Chen -- is responsible
16 personally for everything the company does. And we know from
17 the papers we've submitted to Your Honor he was the head of
18 all their quality organizations, which are the ones who were
19 supposed to prevent this from slipping through and happening.

20 And -- one second, Your Honor. So he's -- so Mr.
21 Chesney says not only is Mr. Chen as the top executive the
22 primary person responsible for everything that happened, but
23 he even talks in the article about criminal penalties and that
24 it would flow up to someone in Mr. Chen's position and confirm
25 that that could apply here. He didn't make a final opinion

1 that it did because there was a lot of facts he was not
2 provided. But his testimony was devastating on that point.
3 He laid everything at the feet of Mr. Chen. That's their own
4 GMP expert, David Chesney.

5 I think that where we come back to is really where we
6 started, and it's a very straight forward situation. The
7 government of China doesn't dictate to the United States
8 judicial system how litigation will proceed in the United
9 States. And this entire argument of, well, what do you want
10 us to do? We're just a company in China. Your Honor hit it
11 right on the head. They chose to do business in the U.S. to
12 make billions of dollars on these drugs. Billions. This
13 company is up and running with a multibillion dollar cap.
14 They are selling the products in the U.S. again, but they just
15 want a pass because their government won't let them give
16 discovery that they've been ordered by federal judges. Well,
17 that's why Judge Kugler's decision says what it says. That's
18 why the decisions he relied on say what they say because,
19 otherwise, if Your Honor were to say, well, you know what?
20 You're right. It's really not ZHP. It's really the Chinese
21 government. That means that every single Chinese company
22 doing business in the U.S. could do whatever they want. And
23 then if they do something wrong, and now the justice system
24 comes down on them, they say, well, sorry. China won't let us
25 participate in that, but thank you for the FDA approval.

1 Thank you for the sale of billions of dollars, et cetera. We
2 all know that could never be permitted. In fact, taking this
3 transcript, I think Your Honor can make a very compelling
4 decision on this to say, here's the arguments we're getting,
5 which are, we're sorry. Nothing I can do about this. And
6 that's exactly why these very significant sanctions should be
7 entered here because everybody needs to know, in this
8 litigation and beyond, the U.S. judicial system is not up for
9 grabs because a country like China decides we're going block
10 people from leaving the country to be deposed. And by the
11 way, one person is going to be blocked. All these other
12 witnesses who were deposed, but he wasn't because they won't
13 let him go, he's special, all of this smacks of being
14 suspicious. But ultimately it doesn't matter how many other
15 witnesses we deposed. He's the guy who we've proven had
16 significant direct involvement. Their own expert, Mr.
17 Chesney, says he is the person who is ultimately responsible
18 for everything. And these violations are so significant in
19 not allowing the chairman of the company to be deposed, I
20 think at this point we can move on from this.

21 The last thing I want to say is counsel is talking
22 about the Hague Convention again. I thought that was already
23 taken care of. The law that we've cited says we don't have to
24 resort to the Hague. We already understand why. We have the
25 Federal Rule of Civil Procedure. ZHP is before this Court.

1 So we did everything appropriately. When counsel says, well,
2 if they really wanted his information, they would've done
3 something more. Well, what else could we do? We fought
4 motions. We had to fight motions on the custodial file. We
5 had to fight protective order on the deposition. We had to go
6 up to Judge Kugler. We're now here seeking the sanctions.
7 We've done everything possible other than going to the defense
8 and saying, well, yeah, we'll take something far less than
9 what we actually need because we want to make life easy. No.
10 We have the right to the discovery that's ordered and
11 appropriate. We're not getting it. There should be no more,
12 you know, come back in another week or two, or month or two
13 and let us know how you feel. This has gone on long enough,
14 and we really believe that the sanctions -- if there's not a
15 case -- if this is a case where it's not appropriate to enter
16 these sanctions, I don't know what case would be based on the
17 law that we have in front of us, and especially on Judge
18 Kugler's decision. So we ask you to award the sanctions we
19 have requested, please.

20 THE COURT: Why would a deposition on written
21 interrogatories be inadequate?

22 MR. SLATER: Well, first of all, you're assuming that
23 we could get him, because remember -- and by the way, I'm glad
24 you asked the question. The so-called law that's blocking him
25 from leaving the country, which has never been actually cited

1 in the briefs and never been laid out and explained to the
2 Court why he really can't leave, why he has to ask for
3 permission, et cetera. All we know is there's some
4 administrative requirement. We have nobody who's actually
5 been knowledgeable, other than the administrative person who
6 said, this is what I submitted, who's actually explained
7 legally why they have the right to flout this Court's
8 discovery order. So that's number one.

9 Number two, why should we be limited to something that
10 Your Honor's already ordered we don't have to be placated
11 with? Even if we could get China to say, fine, submit your
12 written questions, your four written questions. They ask him
13 the questions. We get back whatever we get. There's no
14 follow-up. There's no going through documents. So that would
15 really be inefficient and a waste of time, I think.

16 THE COURT: Mr. Bernardo, brief rebuttal.

17 MR. BERNARDO: First of all, with all respect,
18 plaintiffs' counsel's philosophy of how intercountry juris
19 prudence should work flies in the face of established United
20 States Supreme Court precedence that's been cited by federal
21 courts of appeal. I've already made my argument. I won't
22 repeat it. I disagree with the reading of the opinion that
23 Judge Kugler had and its relevance here.

24 As to the form, Your Honor, first of all, the word
25 "requirements" is in there. Secondly, none of us here are

1 experts or understand the cultural issues and how best to fill
2 out a form in China to try and ensure that it would be
3 granted. And I would suspect that the way in which Mr. Slater
4 described it could almost ensure its rejection by the Chinese
5 government. But, again, my only point here is I don't think
6 there's any deficiency in the form. The fact that we objected
7 to the apex -- on the basis of apex to the deposition going
8 forward, which, as you know, Your Honor, virtually every
9 defendant does when a plaintiff seeks to take the senior most
10 executive. That's an appropriate thing to do. Again, I'm not
11 going to re-litigate that. But because we're exercising our
12 right to make that objection doesn't mean that somehow they
13 didn't act in good faith by way of follow-up in response to
14 the order.

15 And as to Mr. Chesney's report, well, I disagree with
16 the characterization of that testimony in his article. The
17 fact that the buck stops there and that Mr. Chen is
18 responsible doesn't mean that plaintiffs are prejudiced
19 because he somehow has detailed information that they would
20 need. And, in fact, the record establishes and shows the
21 other from the testimony of other witnesses.

22 And, again, you know, these overly broad statements.
23 So this means every Chinese company can do whatever it wants.
24 That's not what we're talking about here. We're not talking
25 about somebody who's flouting this process or procedure here.

1 They're talking about somebody who's trying appropriately to
2 satisfy its discovery obligations while satisfying its own
3 country's obligations. And I think -- and that's even been
4 commented on by Judge Kugler, and perhaps even yourself, the
5 demonstration throughout this process and some of the foreign
6 companies in good faith. So I think for one deposition, to
7 make that statement that a company can do whatever they want,
8 that's not what's going on here and that's not what is at
9 issue.

10 So, again, while -- with respect to the Hague, well, I
11 agree. Plaintiffs don't have to, and Judge Kugler said as
12 much. I was very clear. I'm not disputing that. What I'm
13 saying is when they're up here asking for these extreme
14 sanctions to basically end the case against ZHP, not having
15 tried to do that is a factor for consideration, and Judge
16 Kugler did say that.

17 So, again, Your Honor, the sanctions that are being
18 sought are extreme, are inappropriate, and basically are
19 punishing ZHP, who's otherwise acted in good faith, because of
20 a decision on a single deposition by the Chinese government.

21 THE COURT: Thank you.

22 All right. We'll take the matter under advisement,
23 obviously. It's an extremely important matter. It's a
24 serious matter. I certainly want to explore the question of
25 whether there are lesser sanctions that would be adequate,

1 because I think the inability to take Mr. Chen's deposition
2 is, with all due respect, a serious impediment to plaintiffs'
3 preparation of their case. The particular prejudice, I'm not
4 sure I can articulate right now. I mean, obviously you've
5 been waiting a long time for a ruling on this matter, and I
6 know where things stand. Right now we're at the end at least
7 this part of the case in terms of discovery. I know there's a
8 lot more to be done, and the relief being requested here is,
9 indeed, most serious. So I'm going to take my time to work
10 through this, but it is troubling. I am troubled by the fact
11 that a witness I would regard as an important witness cannot
12 be deposed. I'm not attributing any fault right now to
13 anyone. I'm not saying that anybody's blameless on this
14 matter, but there has to be something that a U.S. litigant can
15 do when they seek testimony from a very significant witness
16 and are precluded from obtaining it.

17 All right. Thank you very much. Anything else for
18 today?

19 MR. SLATER: No, Your Honor. Thank you very much. I
20 appreciate you moving this by a week. Thank you very much.

21 THE COURT: Thank you.

22 MR. BERNARDO: Thank you for taking the time to hear
23 this, Your Honor. I appreciate that.

24 THE COURT: Take care. Bye bye.

25 (Court concludes at 12:41 p.m.)

FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

4 I certify that the foregoing is a correct transcript from
5 the record of proceedings in the above-entitled matter.

I

/S/ Megan McKay-Soule, RDR, CRR September 12, 2022

Court Reporter

Date

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